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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,563	03/29/2004	Victor L. Serebruany	0004.0001-000	1385
42842	7590	10/26/2007		
ANTOINETTE G. GIUGLIANO, P.C. 100 Cummings Center Suite 342G Beverly, MA 01915			EXAMINER PAGONAKIS, ANNA	
			ART UNIT 4173	PAPER NUMBER
			MAIL DATE 10/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/811,563	SEREBRUANY, VICTOR L.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anna Pagonakis	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                           |                                                                                                   |
|-----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                          | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____                                                           |

*DETAILED ACTION*

Per telephone conversation with Antoinette Juliano (see attached Interview Summary), the Restriction Requirement mailed 10/11/2007 is hereby vacated and replaced with the Restriction Requirement and Election of Species detailed below.

Due to the complex nature of claims, no request for oral election is being made. Please see MPEP 812.01.

In addition to the Restriction Requirement, Election of Groups I or III also require an additional Election of Species.

*Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, 22, 23 and 27-28, drawn to a method of treating a vascular disorder by selecting an individual having an elevated G-coupled Protease Activating Receptor (PAR)-1 level, an elevated PAR-4 level, or both; and administering an effective amount of statin to an individual. Please note additional Election of Species Requirement outlined below if Group I is elected.
- II. Claims 15-17 and 24, drawn to a method of treating an individual with a vascular disorder by selecting an individual that has a vascular disorder and by administering an effective amount of statin.
- III. Claims 18-21 and 25-26, drawn to a method of reducing thrombin generation in an individual by seeking an individual that has a vascular disorder and by

Art Unit: 4173

administering to an individual an effective amount of statin. Please note additional

Election of Species Requirement outlined below if Group III is elected.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are directed to methods of treatment one of a vascular disorder and the other of a thrombin generation. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function or effect; (2) the inventions do not overlap, i.e., are mutually exclusive; and (3) the inventions as claimed encompass related methods of treating a vascular disorder or thrombin generation. For example, the mode of administration of Groups I, II and III are entirely different. Furthermore, Group II is in regards to treatment of thrombin generation while I-II are directed to treatment of a vascular disorder. As such, the search required for Groups I, II and III would not be the same. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

These inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required. Because the inventions required a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

*Election of Species Requirement*

Applicant is reminded that under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, with the election of Groups I or III, applicant is required to elect:

one vascular disorder (see instant claims 5, 12, 19)

one statin (see instant claims 6, 14, 21)

If applicant elects a specie from the above specie election which is not found in the instant disclosure as filed, specie election may be considered new matter.

MPEP 809.02 states “[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claim recite such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all the claimed species were to be examined simultaneously.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant is entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must include which are readable upon the elected species. See MPEP 809.02(a).

Art Unit: 4173

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions above are patentably distinct. The search for each of the above inventions is not co-existence particularly with regard to the literature search. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious the other group. Finally, the consideration for patentability is different in each case. Thus, it would be undue burden to examine all of the above inventions in one application and the restriction for examination purposes as indicated above is deemed proper.

#### *Inventorship Notice*

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 4173

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Transition Notice***

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or **THIRTY DAYS**, whichever is longer, from the mailing date of

Art Unit: 4173

this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Pagonakis whose telephone number is 571-270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER